

DOCUMENT RESUME

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[Adequacy of HEW's Audit of Swine Flu Vaccine Manufacturing Costs]. HRD-78-163; B-164031(5). September 19, 1978. 3 pp.

Report to Rep. George E. Danielson, Chairman, House Committee on the Judiciary: Administrative Law and Governmental Relations Subcommittee; Rep. Paul G. Rogers, Chairman, House Committee on Interstate and Foreign Commerce: Health and the Environment Subcommittee; Rep. John E. Moss, Chairman, House Committee on Interstate and Foreign Commerce: Oversight and Investigations Subcommittee; Rep. John D. Dingell, Chairman, House Committee on Interstate and Foreign Commerce: Energy and Power Subcommittee; Rep. Jack Brooks, Chairman, House Committee on Government Operations; Rep. Walter Flowers; by Elmer B. Staats, Comptroller General.

Issue Area: Federal Procurement of Goods and Services:

Reasonableness of Prices Under Negotiated Contracts and Subcontracts (1904); Health Programs: Federal Government Control of Costs Through Direct Delivery Programs (1216).

Contact: Human Resources Div.

Budget Function: Health: Prevention and Control of Health Problems (553).

Organization Concerned: Department of Health, Education, and Welfare; Merck, Sharp, and Dohme; Wyeth Labs.; Merrell-National Labs.; Parke, Davis and Co.

Congressional Relevance: House Committee on the Judiciary: Administrative Law and Governmental Relations Subcommittee; House Committee on Interstate and Foreign Commerce: Health and the Environment Subcommittee; House Committee on Interstate and Foreign Commerce: Oversight and Investigations Subcommittee; House Committee on Interstate and Foreign Commerce: Energy and Power Subcommittee; House Committee on Government Operations; House Committee on Interstate and Foreign Commerce; Senate Committee on Human Resources. Rep. George E. Danielson; Rep. Paul G. Rogers; Rep. John E. Moss; Rep. John D. Dingell; Rep. Jack Brooks; Rep. Walter Flowers.

A review of the Department of Health, Education, and Welfare's (HEW's) audit of swine flu vaccine manufacturing costs showed that final procedures used by HEW to audit the costs claimed by Merck, Sharp, and Dohme; Wyeth Laboratories; and Merrell-National Laboratories were adequate. During the review, proposals were made that HEW perform additional audit work to provide a better basis for reaching its audit conclusions or to obtain information with which the auditors could render an opinion on costs they formerly considered unresolved. Additional efforts by the auditors resulted in an adequate audit. Judgments on final contract prices to be negotiated with manufacturers were left to HEW, but a proposal was made to the contracting officer that imputed interest be computed after final costs are

negotiated. The HEW audit of the Parke-Davis contract was delayed because of a contract dispute, but HEW has requested and received cost data from the company pending resolution of the dispute and has started its audit. (HTW)



COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(5)

SEPTEMBER 19, 1978

The Honorable George E. Danielson, Chairman
Subcommittee on Administrative
Law and Governmental Relations
House Committee on the Judiciary

The Honorable Walter Flowers
House of Representatives

The Honorable Paul G. Rogers, Chairman
Subcommittee on Health and the Environment
House Committee on Interstate and Foreign Commerce

The Honorable John E. Moss, Chairman
Subcommittee on Oversight and Investigations
House Committee on Interstate and Foreign Commerce

The Honorable John D. Dingell, Chairman
Subcommittee on Energy and Power
House Committee on Interstate and Foreign Commerce

The Honorable Jack Brooks, Chairman
House Committee on Government Operations

In August and October 1976, you requested that we review various aspects of the swine flu program, including the adequacy of the Department of Health, Education, and Welfare's (HEW's) audit of vaccine manufacturing costs. Our report, "The Swine Flu Program: An Unprecedented Venture in Preventive Medicine" (HRD-77-115, June 27, 1977), focused on HEW's implementation of the program; this letter addresses the adequacy of HEW's audit.

In our opinion the final procedures used by HEW to audit the costs claimed by three manufacturers--Merck, Sharp, and Dohme; Wyeth Laboratories; and Merrell-National Laboratories--were adequate. HEW recently began auditing the fourth manufacturer--Parke, Davis, and Company--and we will monitor the audit as it proceeds.

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(102031)

During our review we proposed that HEW perform additional audit work for each of the three manufacturers to (1) provide a better basis for reaching its audit conclusions or (2) obtain information with which the auditors could render an opinion on costs they formerly considered unresolved. We made our proposals to HEW for additional work at Merck and Wyeth after its auditors had completed their work at these manufacturers; HEW's audit of Merrell-National was still in process when we made our proposals. The type and extent of additional audit work we proposed varied by manufacturer and by cost element. In summary, we proposed that the auditors:

- Go beyond tracing purchase transactions to vendor invoices by also verifying that payment had been made and that the amount paid was at invoice prices, thus providing greater assurance that material purchase costs were actually incurred.
- Trace summary data presented by the manufacturers back to supporting documents and, when selecting a small sample of a cost element for review, review the entire sample.
- Obtain sufficient evidence to determine the extent that all claimed costs for vaccine production relate to contract performance.
- Determine conclusively the availability of support documents so that as many cost elements as possible can be classified as either acceptable or unacceptable, rather than being classified as unresolved.
- Determine whether costs attributable to field selling, marketing, and research are allowable or should be allocated to vaccine production. (These costs for one manufacturer totaled about \$1.5 million and about 10 percent of the vaccine contract's value. The manufacturer claimed these costs had been previously accepted by the contracting officer.)

We believe that the HEW auditors' additional efforts have resulted in an adequate audit.

Final contract prices will be negotiated with the manufacturers by the HEW contracting officer. To avoid limiting HEW's negotiating freedom, we commented only on

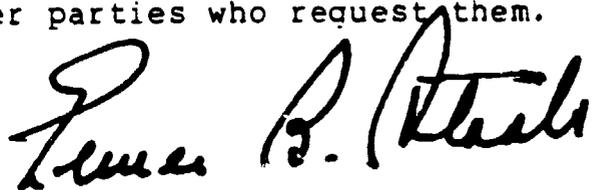
the adequacy of audit procedures and left judgments as to the reasonableness of particular cost elements to HEW. We have, however, proposed to the contracting officer that imputed interest be computed after final costs are negotiated, so that interest is paid only on allowable costs.

The contracting officer expects negotiations to begin in October. He has received the final audit report for Wyeth, and expects to receive the reports for Merck and Merrell-National by the end of September. He plans to obtain advice and assistance from the auditors during the negotiations.

The HEW audit of the Parke-Davis contract was delayed because of a contract dispute over the allowability of costs incurred for the production of a Shope strain flu vaccine which was mistakenly produced for the swine flu program. HEW would not approve the use of the vaccine during the program or pay for its production costs under the swine flu vaccine contract. The dispute is being reviewed by the Armed Services Board of Contract Appeals, and as of September 1, 1978, the Board had made no decision. HEW requested Parke-Davis to submit its cost data and allow the auditors access to the cost records so that audit work could begin on costs which are not in dispute. Parke-Davis has complied with this request and HEW has begun its audit. We plan to monitor the audit as it proceeds and will report back to you when we have evaluated its adequacy.

We welcome the opportunity to discuss the details of the above matters with you or your staff.

As arranged with your offices, we are sending copies of this report to the Secretary of Health, Education, and Welfare; the Director, Office of Management and Budget; and the Director, Center for Disease Control. Copies will also be available to other parties who request them.



Comptroller General
of the United States